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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,657	11/18/2003	Nady E. Nady	RWJ 05-69	5354

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UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY
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EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/715,657	NADY, NADY E.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 2,9,18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Claim Objections

2. Claims 2 and 9 are objected to because of the following informalities: Claims 2 and 9 contain improper grammar. The term "locating" should be changed to "located". Appropriate correction is required.
3. Claim 18 is objected to because of the following informalities: Claim 18 is dependent on a "method according to claim 15". Claim 15 is a device, not a method. For examination purposes, claim 18 has been interpreted as being dependent on claim 17, not claim 15. Appropriate correction is required.
4. Claim 19 is objected to because of the following informalities: Claim 19 is dependent on a "method according to claim 16". Claim 16 is a device, not a method. For examination purposes, claim 19 has been interpreted as being dependent on claim 18, not claim 16. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3731

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Ackerman (Patent No. 5,624,399).

It is noted that the applicant is invoking 112 6th paragraph. Regarding claim 1, Ackerman discloses an inflatable housing (Figure 2, element 38) adapted to be received on an outer portion of a tubular body of a diagnostic or surgical instrument. Figure 2 shows an inflatable housing (38) surrounding an outer diameter of a tubular body (32) of a diagnostic or surgical instrument (30). Means for inflation includes an appendage (50), connector (54), and inflation device (comprising elements 56 and 58). The inflation device utilizes saline or air to inflate the inflatable housing (column 3, lines 60-63). Figure 4A shows a seal between the outer portion of the tubular body (32) of the diagnostic or surgical instrument (30) and a wall of the body canal (24). Regarding claim 2, Figures 4A and 4B show that the means for inflating the inflatable housing (38) is located outside the body canal (24). Regarding claim 3, Ackerman discloses that the inflatable housing (38) is made from an elastomeric material (polyurethane; column 2, lines 42-45).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Art Unit: 3731

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 8-9 and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Loy (Patent No. 6,485,410 B1).

It is noted that the applicant is invoking 112 6th paragraph. Regarding claim 8, Loy discloses an inflatable housing (Figure 1, element 31) adapted to be received on an outer portion of a tubular body of a hysteroscope instrument. Figure 1 shows an inflatable housing (31) surrounding an outer diameter of a tubular body (20) of a hysteroscope instrument (10). Means for inflation includes an appendage (33), connector (32), and inflation device (not shown) that is used to inject a liquid through the connector (column 2, lines 66-67). Once the inflatable housing (31) is placed on the hysteroscope instrument (10), it is inflated to dilate the cervix and to maintain the cervix in the dilated state (column 1, lines 62-63). Therefore, it is inherent that the inflatable housing (31) provides a seal between the outer portion of the body of the hysteroscope instrument (10) and a wall of the cervical canal upon inflation. Regarding claim 9, Loy discloses that the hysteroscope instrument (10) is inserted into the vagina with the distal tip protruding the uterus and with the balloon located in the cervix (column 3, lines 27-29). Therefore, it is inherent that the means for inflation is located outside the cervical canal.

It is noted that the applicant is invoking 112 6th paragraph. Regarding claim 17, Loy discloses placing a device (Figure 1, element 31) with means for inflating the device (appendage (33), connector (32), and inflation device (not shown)) over a tubular portion (20) of a hysteroscope instrument (10). Loy discloses inserting the hysteroscope

instrument (10) into the cervical canal so that the device is positioned within the cervical canal and an outer portion of the device is adjacent to the walls of the cervical canal (column 3, lines 25-29). Loy also discloses inflating the device (31) with means for inflating (column 3, lines 31-33) to dilate the cervix and to maintain the cervix in the dilated state (column 1, lines 61-63). Therefore, it is inherent that the inflated device (31) provides a seal between the outer portion of the body of the hysteroscope instrument (10) and a wall of the cervical canal for preventing the fluid or gas from the uterus from flowing out of the cervical canal during use of the hysteroscope instrument (10). Regarding claim 18, Loy discloses deflating the device and withdrawing the hysteroscope (column 3, lines 36-38).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackerman in view of Norelli et al. (Patent No. 5,342,385).

Regarding claims 4-6, Ackerman discloses an inflatable housing as described in claim 3, but does not disclose the structure of the inflatable housing. Norelli et al. disclose an inflatable housing (Figure 7, element 32) used to retract a vaginal canal, or any other desired location, for certain procedures (column 4, lines 25-27). As noted therein, the inflatable housing comprises a plurality of layers, inner layer (24) and outer layer (26), which are sealed by forward wall (28) and rearward end wall (30). Each layer is comprised of a material that has elastic properties so as to be expandable to fit the particular incision or opening (column 4, lines 28-31). The inner layer (24) is rigid, comprising a durable material to prevent punctures or incisions that may be inflicted by the surgeon working through the opening of the inflatable housing (column 4, lines 34-40). Therefore, to construct the inflatable housing of Ackerman with a plurality of layers, the inner layer being rigid, independently made from elastomeric material would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide an expandable housing that can fit the particular body canal, and is resistant to punctures or incisions as the inflatable housing is slid onto a surgical or diagnostic instrument.

Regarding claim 7, Ackerman discloses an inflatable housing as described in claim 1, but does not disclose that the inflatable housing is disposable. Norelli et al. disclose a disposable inflatable housing to avoid the expense of sterilization and/or the risks of faulty sterilization (column 2, lines 18-20). Therefore, to modify the inflatable

housing of Ackerman to make it disposable would have been obvious to one of ordinary skill in the art at the time the invention was made in order to eliminate unnecessary sterilization expenses and avoid cross-contamination between patients.

12. Claims 10-13, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loy in view of Norelli et al.

Regarding claims 10-13, Loy discloses an inflatable housing as described in claim 8, but does not disclose the structure of the inflatable housing. Norelli et al. disclose an inflatable housing (Figure 7, element 32) used to retract a vaginal canal, or any other desired location, for certain procedures (column 4, lines 25-27). As noted therein, the inflatable housing comprises a plurality of layers, inner layer (24) and outer layer (26), which are sealed by forward wall (28) and rearward end wall (30). Each layer is comprised of a material that has elastic properties so as to be expandable to fit the particular incision or opening (column 4, lines 28-31). The inner layer (24) is rigid, comprising a durable material to prevent punctures or incisions that may be inflicted by the surgeon working through the opening of the inflatable housing (column 4, lines 34-40). Therefore, to construct the inflatable housing of Loy with a plurality of layers, the inner layer being rigid, independently made from elastomeric material would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide an expandable housing that can fit a cervical canal, and is resistant to punctures or incisions as the inflatable housing is slid onto a hysteroscope instrument.

Regarding claim 16, Loy does not disclose that the inflatable housing described in claim 8 is disposable. Norelli et al. disclose a disposable inflatable housing to avoid

the expense of sterilization and/or the risks of faulty sterilization (column 2, lines 18-20). Therefore, to modify the inflatable housing of Loy to make it disposable would have been obvious to one of ordinary skill in the art at the time the invention was made in order to eliminate unnecessary sterilization expenses and avoid cross-contamination between patients.

Regarding claim 19, Loy discloses a method as described in claim 17, but does not disclose disconnecting, removing, and disposing the device. Norelli et al. disclose a disposable inflatable housing to avoid the expense of sterilization and/or the risks of faulty sterilization (column 2, lines 18-20). Therefore, to modify the inflatable housing of Loy to make it disposable would have been obvious to one of ordinary skill in the art at the time the invention was made in order to eliminate unnecessary sterilization expenses and avoid cross-contamination between patients. It is obvious that one would have to disconnect the means for inflating the device and remove the device from the hysteroscope instrument prior to disposing the device.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loy in view of Muller (Patent No. 5,392,765).

Loy discloses a device as described in claim 8, but does not disclose a hysteroscope sleeve. Muller discloses a continuous flow hysteroscope that utilizes a sleeve (Figure 1, element 22) to irrigate an operative site (column 2, lines 3-7). This system provides sufficient flow and pressure to distend and expand the uterus to enable the surgeon to perform the desired procedure (column 1, lines 63-66), without exceeding levels that are undesirable in performing the procedure (column 1, lines 59-

62). Therefore, to modify the hysteroscope of Loy so that the outer portion of the tubular body is a sleeve would have been obvious to one of ordinary skill in the art at the time the invention was made in order to create a continuous flow system for controlled irrigation of the uterine cavity.

14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loy in view of Muller as applied to claim 14 above, and further in view of Sinnreich (Patent No. 3,882,852).

Loy discloses a device as described in claim 8. Muller discloses a hysteroscope sleeve as described in claim 14, but does not disclose that the device is permanently attached to an outer portion of the hysteroscope sleeve. Sinnreich discloses an inflatable housing (elongated expandable membrane; Figure 2, element 16) that is permanently attached, or "bonded", to the surface of a sleeve (rigid shaft member, 11) in which an hysteroscope (endoscope; Figure 4, element 51) may be positioned (column 2, lines 28-31). To modify the device of Loy so that the device is permanently attached to an outer portion of a hysteroscope sleeve would have been obvious to one of ordinary skill in the art at the time the invention was made in order to provide a device capable of maintaining a substantially uniform expansive pressure along the longitudinal axis of the sleeve.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-

Art Unit: 3731

9062. The examiner can normally be reached on Monday through Friday 7:30 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Tyson
April 11, 2006


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/15/06.